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PATENT  
Docket No. 359292000101

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Assistant Commissioner for Patents, Washington, D.C. 20231, on August 10, 1998.

  
LaVerne Whetstone



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Geroge H. LOWELL

Serial No.: 08/677,302

Filing Date: July 9, 1996

For: ORAL OR INTRANASAL VACCINES  
USING HYDROPHOBIC COMPLEXES  
HAVING PROTEOSOMES AND  
LIPOPOLYSACCHARIDES

Examiner: J. Shaver

Group Art Unit: 1802

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DECLARATION OF GEORGE H. LOWELL  
PURSUANT TO 37 C.F.R § 1.132

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, George Lowell, M.D., declare as follows:

1. I am an inventor of the above-referenced patent application, and am familiar with the contents thereof.
2. I am a co-author of an article entitled "Immunogenicity and Efficacy of Oral or Intranasal Shigella flexneri 2a and Shigella sonnei Proteosome-Lipopolysaccharide Vaccines in Animal Models," Infection and Immunity, volume 61, No. 6

(June, 1993), pp. 2390-2395, an abstract (C. P. Mallett et al.) entitled "Oral or Intranasal Vaccination with Proteosome-Shigella sonnei LPS Complexes Protect Against Lethal Pneumonia in a Mouse Model" (E-58) and an abstract (N. Orr et al.) entitled "Oral or Intranasal Proteosome-Shigella LPS Vaccines Induce Serum IgG and Secretory IgA in Mice and Protect Guinea Pigs Against S. Sonnei or S. Flexneri 2a Keratoconjunctivitis" (E-59) ( both abstracts are from the 93rd General Meeting of the American Society for Microbiology, Atlanta, Georgia, USA, May 16-20, 1993. Abstract Gen. Meet. Am Soc. Microbiol). I am the sole inventor of the subject mater which is disclosed in these publications and disclosed and claimed in the above-referenced patent application.

3. In addition to myself, there are four other co-authors (Nadav Orr, Guy Robin, Dani Cohen and Ruth Arnon) listed on the Infection and Immunity article, four other co-authors (C. P. Mallett, N. Orr, D. Cohen and T. L. Hale) listed on the E-58 abstract and five other co-authors (N. Orr, G. Robin, E. Aboud-Pirak, R. Arnon and D. Cohen) listed on the E-59 abstract, they are not co-inventors of the subject matter described therein.
4. Two of the co-authors, Nadav Orr (N. Orr) and Guy Robin (G. Robin) were graduate students and members of the Israel Defense Forces working, under my direct supervision and control, in my laboratory in Israel, as technical research assistants on the experiments described in the publication.
5. Dani Cohen ( D. Cohen) was the officer in the Israel Defense Force who was responsible for assigning Nadav Orr and Guy Robin to work in my laboratory and also provided assistance in the form of space and material from the Israel Defense Forces to help accomplish the experiments described in the publication. For these

reasons, Dani was named as a co-author on the publication to reflect this support of the research.

6. Ruth Arnon (R. Arnon) was my hostess at the Weizmann Institute of Science who invited me to do my research as a visiting scientist and Medical Liaison Officer working in the U.S. Army from the Walter Reed Army Institute of Research with duty station at the Weizmann Institute. Accordingly, she helped provided space and material to accomplish the research and was listed as a co-author to acknowledge this contribution of support.
7. Ester Aboud-Pirak (E. Aboud-Pirak) was on the E-59 abstract but not the cited article. She was a junior microbiologist working in my lab mostly on other projects. Her contribution was enough to be included on the abstract but not enough to be included on the paper.
8. T. L. Hale and C. P. Mallett had previously used the lethal mouse protection assay referred to in the E-58 abstract.
9. T. L. Hale, the department chief of C. P. Mallett, provided space, money and people in addition to the prior experience with the lethal mouse protection assay (model).
10. C. P. Mallett did work as a junior microbiologist under my direction and control.
11. The four additional individuals (Nadav Orr, Guy Robin, Dani Cohen and Ruth Arnon) named as co-authors in the cited article, the four additional individuals (C. P. Mallett, N. Orr, D. Cohen and T. L. Hale) named as co-authors in the cited E-58 abstract and the five additional individuals (N. Orr, G. Robin, E. Aboud-Pirak, R. Arnon and D. Cohen) named as co-authors in the cited E-59 abstract were not inventors of the subject matter described in the cited article or the cited E-58 and E-58 abstracts or in the presently pending application, but were listed as co-authors of the article or the

abstracts, respectively, in order to receive credit for having collaborated in the research program under my direction and control and/or contributed to the program by providing materials, laboratory space and support or funding.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed:

Date

26 Aug 98

George H. Lowell